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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/02 — A1

(11) International Publication Number: WO 95/30374

(43) International Publication Date: 16 November 1995 (16.11.95)

(21) International Application Number: PCT/US95/05430

(22) International Filing Date: 5 May 1995 (05.05.95)

(30) Priority Data:
08/239,233 6 May 1994 (06.05.94) US

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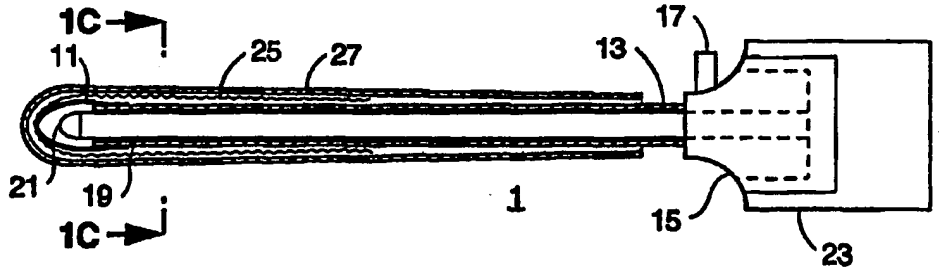
(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: APPARATUS AND METHOD FOR DELIVERING A PATCH



(57) Abstract

An apparatus for delivering a mesh patch during a surgical procedure, especially during a laparoscopic surgical procedure. The apparatus comprises an elongate cannula (13) having a balloon (11) mounted on its distal end. The mesh patch (25) is wrapped around part of the cannula and the balloon with the balloon in a collapsed state. The apparatus may also include a detachable sleeve (27) enclosing the balloon and the mesh patch. A method laparoscopically delivering a mesh patch to a site of surgery inside a patient is disclosed. In the method, a balloon is provided having the mesh patch wrapped around it. The balloon is in a collapsed state. The balloon wrapped in the mesh patch is passed through the patient's skin to locate the balloon wrapped in the mesh patch adjacent the site of surgery. Finally, the balloon is inflated to an expanded state. Expansion of the balloon to the expanded state opens and flattens the mesh patch to apply the mesh patch to the site of surgery.

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APPARATUS AND METHOD FOR DELIVERING A PATCH

Field of the Invention

The invention generally relates to an apparatus and method for delivering a mesh patch during surgery, especially during laparoscopic surgery. More particularly, the invention relates to an apparatus and method for delivering a mesh patch during hernia repair, and to a method of performing a hernia repair.

Background of the Invention

A hernia is the protrusion of a portion of a body part or structure through a defect in the wall of a surrounding structure. Most commonly, a hernia is the protrusion of part of the abdominal contents, including bowel, through a tear or weakness in the abdominal wall, or through the inguinal canal into the scrotum.

An abdominal hernia is often repaired by suturing a mesh patch, which is an appropriately sized piece of surgical mesh, such as polypropylene or Gortex™, over the site of the tear or weakness. Recently, laparoscopic techniques to perform hernia repair are becoming increasingly common. In such techniques, the mesh patch is commonly rolled up into a cylindrical form, which is then pushed through a trocar tube to a location adjacent the site of the hernia. Then, using laparoscopic instruments inserted through one or more trocar tubes, the surgeon unrolls the rolled-up mesh patch, flattens the mesh patch, and positions the mesh patch over the site of the hernia. This is a tedious and time-consuming process.

Recent techniques involve the use of large mesh patches, for example, of the order of 150 mm × 75 mm, which compound the problems of unrolling, flattening, and positioning the mesh patch using conventional laparoscopic techniques. Moreover, the maximum size of the mesh patch is limited by the size of mesh patch that will pass in a rolled state through a large (e.g., 14 mm) trocar tube.

United States patent no. 5,309,896, the disclosure of which is incorporated herein by reference, discloses a method of delivering a mesh patch in the course of a properitoneal laparoscopic hernia repair procedure. The mesh patch is attached to the outside surface of the envelope of the structural balloon used to dissect the peritoneum away from the properitoneal layer, and to provide access to the site of the hernia. However, not all laparoscopic hernia repair techniques use a structural balloon that is left in place while the hernia is being repaired. Moreover, the mesh patch attached to the outside surface of the structural balloon can obstruct access to the site of the hernia by laparoscopic instruments passed through the main chamber of the structural balloon.

Objects and Summary of the Invention

It is an object of the invention to provide an apparatus and method for delivering a mesh patch to a site of surgery in the body in the course of a surgical procedure.

It is an object of the invention to provide an apparatus and method for flattening the delivered mesh patch at the site of surgery in the body.

It is an object of the invention to provide an apparatus and method for applying the flattened mesh patch to cover the site of surgery in the body.

It is an object of the invention to provide an apparatus and method for delivering a mesh patch considerably larger than the size of mesh patches that can be delivered by known laparoscopic delivery techniques.

Accordingly, the invention provides an apparatus for delivering a mesh patch during a surgical procedure, especially during a laparoscopic surgical procedure. The apparatus comprises an elongate cannula having a balloon mounted on its distal end. The mesh patch is wrapped around part of the cannula and the balloon with the balloon in a collapsed state. The apparatus may additionally include a detachable sleeve enclosing the mesh patch and the balloon. The apparatus also may include an arrangement for detachably attaching the mesh patch to the balloon.

The invention also provides a method of delivering a mesh patch to a site of surgery inside a patient. In the method, a balloon is provided having the mesh patch wrapped around it. The balloon is in a collapsed state. The balloon wrapped in the mesh patch is passed through the patient's skin to locate the balloon wrapped in the mesh patch adjacent the site of surgery. Finally, the balloon is inflated to an expanded state. Expansion of the balloon to the expanded state opens and flattens the mesh patch to apply the mesh patch to the site of surgery.

Finally, the invention provides a method of performing a hernia repair, preferably laparoscopically. In the method, a mesh delivery apparatus is provided. The mesh delivery apparatus includes a balloon attached to the distal end of an elongate cannula. The mesh patch is wrapped around the balloon and part of the cannula. A detachable sleeve encloses the balloon and the mesh patch. Next, in the method, a working space is created adjacent the hernia. The distal part of the mesh delivery apparatus is inserted into the working space to locate the balloon adjacent the hernia. The balloon is inflated to an expanded state. The expansion of the balloon to the expanded state opens and flattens the mesh patch and applies the mesh patch to cover the hernia.

Brief Description of the Drawings

Figure 1A is a side view showing an embodiment of the mesh delivery apparatus according to the invention in its packaged state.

Figure 1B is a longitudinal cross-sectional view of the mesh delivery apparatus shown in Figure 1A.

Figure 1C is a transverse cross-sectional view of the mesh delivery apparatus shown in Figure 1A.

Figure 2 is a side view showing the mesh delivery apparatus shown in Figure 1A after expansion of the balloon.

Figure 3A is a side view showing the mesh delivery apparatus according to the invention after expansion of the balloon. The mesh patch is attached to the balloon in an on-axis configuration by a small patch of adhesive.

Figure 3B is a side view showing the mesh delivery apparatus according to the invention after expansion of the balloon. The mesh patch attached to the balloon in an off-axis configuration by a small patch of adhesive.

Figure 4 is a side view showing the mesh delivery apparatus according to the invention after expansion of the balloon. The mesh patch is attached to the balloon in an on-axis configuration by the hooks of the hook component of a hook-and-loop connector engaging in the mesh patch.

Figure 5 is a longitudinal cross-sectional view showing part of the balloon and the mesh patch. The mesh patch is attached to the balloon by a wire hook running in a block attached to the balloon.

Figure 6A is a side view of an embodiment of the mesh delivery apparatus according to the invention in which the mesh patch is attached to the balloon using strings. The apparatus is shown in its packaged state.

Figure 6B shows how the strings are looped through the mesh patch before the mesh patch is attached to the balloon in the mesh delivery apparatus shown in Figure 6A.

Figure 6C shows the mesh delivery apparatus shown in Figure 6A after expansion of the balloon. The mesh patch is attached to the balloon in an on-axis configuration by the strings looped through the mesh patch and passing though an O-ring mounted on the cannula.

Figure 7A is a side view of an embodiment of the mesh delivery apparatus according to the invention having an alternative configuration of the sleeve. The apparatus is shown in its packaged state.

Figure 7B is a transverse cross-sectional view of the mesh delivery apparatus shown in Figure 7A.

Figure 8 is a longitudinal cross-sectional view of the balloon showing an arrangement for attaching an endoscope to the balloon.

Figure 9A is a longitudinal cross-sectional view of the lower abdomen after a working space has been created between the peritoneum and the properitoneal layer.

Figure 9B is a plan view of the lower abdomen showing the outline of the working space and the tunnel leading to the working space from an incision at the umbilicus.

Figure 9C is a plan view of the lower abdomen showing the distal end of the mesh delivery apparatus inserted into the tunnel between the umbilicus and the working space.

Figure 9D is a plan view of the lower abdomen showing the distal end of the mesh delivery apparatus inserted into the working space, and an endoscope substituted for the blunt-tipped obturator in the cannula.

Figure 9E is a plan view of the lower abdomen showing the mesh delivery apparatus after the balloon has been partially inflated and the sleeve has been removed.

Figure 9F is a view inside the working space showing how partially inflating the balloon releases the mesh patch from its wrapped state.

Figure 9G is a view inside the working space showing how fully inflating the balloon opens and flattens the mesh patch.

Figure 9H is a view inside the working space showing the balloon returned to a partially-inflated state, leaving the mesh patch attached to the abdominal wall.

Figure 9I is a view inside the working space showing how the balloon is detached from the mesh patch.

Figure 10A is a longitudinal cross-sectional view of the lower abdomen showing a working

space created and maintained by a structural balloon inserted between the peritoneum and the properitoneal layer.

Figure 10B is a longitudinal cross-sectional view of the lower abdomen showing an incision made through the abdominal wall to gain access to the interior of the structural balloon through a window in the top surface.

Figure 10C is a longitudinal cross-sectional view of the lower abdomen showing the mesh delivery apparatus inserted through the incision and the top window into the interior of the structural balloon.

Figure 10D is a longitudinal cross-sectional view of the lower abdomen showing the mesh delivery apparatus after the sleeve has been detached and removed by pulling on the removable lacing.

Figure 10E is a longitudinal cross-sectional view of the lower abdomen showing how fully inflating the balloon opens and flattens the mesh patch.

Figure 10F is a longitudinal cross-sectional view of the lower abdomen showing the mesh patch in place over the hernia, and the mesh delivery apparatus removed from the working space.

Detailed Description of the Invention

The mesh delivery apparatus 1 is shown in its collapsed, packaged state in Figures 1A - 1C, and in its expanded state in Figure 2. Referring to these Figures, in the mesh delivery apparatus 1, the balloon 11 is attached to the distal end of the cannula 13. With the balloon in a collapsed state, the mesh patch 25 is roughly centered on the balloon, and is then wrapped around the balloon and the outside of the cannula. The mesh patch may be retained in its wrapped state by the detachable sleeve 27 or other suitable means.

The blunt-tipped obturator 19 may be inserted into the cannula 13. The distal tip 21 of the blunt-tipped obturator projects beyond the distal end of the cannula 13 into the balloon 11. The obturator 19 may be rigid or slightly flexible. The distal tip of the blunt-tipped obturator and the sleeve 27 provide the mesh delivery apparatus 1 with a firm, rounded nose that enables the mesh delivery apparatus to be inserted into the patient's body through the skin, without the need for a trocar tube.

Once the mesh delivery apparatus 1 has been inserted into the patient's body, the endoscope E may be substituted for the blunt-tipped obturator 19 in the cannula 13. The endoscope may then be used to aid the surgeon in correctly locating the distal end of the mesh delivery apparatus, and hence the center of the mesh patch 25, relative to the site of surgery.

The balloon 11 is preferably made of an elastic material, such as latex, polyurethane, or silicone, and is preferably a silicone rubber molding. Alternatively, the balloon 11 may be made of a relatively inelastic material, such as a polyester/polyurethane composite film. The composite film has, for example, a core of a nylon or polyester fabric about 0.5 to 2 mil. (12-50 μm) thick. The fabric can be a woven fabric, or can be a layer of randomly-oriented fibres. The core is laminated between two polyurethane films, which bond securely to the uneven surface of the core, to provide a composite film with a preferred thickness of about 3 mil. (75 μm). Such a composite material provides the benefits of both polyester and polyurethane simultaneously.

The balloon 11 is illustrated as having a generally spherical shape, but may also be

fabricated to have an elongated or asymmetrical shape to provide optimum mesh placement in certain procedures, or to provide particular dissection paths during inflation.

In an embodiment for use in inguinal hernia repair, the cannula 13 has a diameter of about 10 mm, and a length of about 200 mm. The proximal end of the cannula 13 is fitted with the port 15. The port 15 includes the valve 17, through which an inflation fluid can be passed to expand the balloon 11. The proximal face (not shown) of the port 15 includes a flap valve (not shown) that forms a fluid-tight seal with instruments passed through it into the cannula 13, and also provides a fluid-tight seal for the cannula when no instrument is passed through it.

Figures 1A-1C also show the mesh delivery apparatus 1 with the blunt-tipped obturator 19 passed through the port 15 into the cannula 13. The blunt-tipped trocar aids insertion of the mesh delivery apparatus 1 into the body through an incision in the skin, as will be described in detail below. The dimensions of the blunt-tipped obturator 19 are such that the distal tip 21 of the obturator projects beyond the distal end of the cannula 13, into the unexpanded balloon 11. The blunt-tipped obturator provides the mesh delivery apparatus 1 with a firm, rounded nose that makes it easier to insert the apparatus into an incision and to perform blunt dissection using the apparatus, and provides tactile feedback. The handle 23 of the obturator mates with the port 15. An endoscope E may later be substituted for the blunt-tipped obturator in the cannula 13, as shown in Figure 2, which will be described below.

The mesh delivery apparatus 1 is preferably packaged together with the mesh patch 25 prior to use. The mesh patch can be made of polypropylene, Gortex™, or other material suitable for the particular surgical application. The mesh patch is roughly centered on the center of uninflated balloon 11, and is drawn back along the outside of the cannula 13, as shown in Figure 1A. To minimize the outside diameter of the mesh delivery apparatus 1 in its packaged state, the mesh patch is spirally wrapped around the outside of the cannula. If the balloon 11 is made of an inelastic material, the balloon is also wrapped around the outside of the cannula, together with the mesh patch. The sleeve 27 may be used to maintain the mesh patch and, if necessary, the balloon, in their wrapped condition. The sleeve will be described in more detail below.

In the construction of the mesh delivery apparatus 1 just described, the mesh patch 25 is not attached to the mesh delivery apparatus 1. This affords the simplest construction of the apparatus, and, in one respect, the simplest operation, because, after the mesh patch has been deployed, the mesh patch is self-detaching from the mesh delivery apparatus. However, it is sometimes desirable to have the ability to reposition the mesh patch relative to the site of surgery after the mesh patch has been initially deployed by expanding the balloon 11. Attaching the mesh patch to the mesh delivery apparatus enables the surgeon to use the mesh delivery apparatus 1 to manipulate the mesh patch to optimize the position of the mesh patch relative to the site of surgery. Hence, the mesh patch 25 may be releasably attached to the mesh delivery apparatus 1.

Figures 3A through 7B show various arrangements for attaching the mesh patch 25 to the mesh delivery apparatus 1. Figure 3A shows the mesh patch attached to a portion of the balloon that lies on the longitudinal axis of the cannula 13. With the mesh patch attached in this way, the mesh patch is deployed in a plane roughly perpendicular to the axis of the cannula when the balloon is expanded. The attachment point between the balloon and the mesh patch can alternatively lie off the axis of the cannula, as shown in Figure 3B. This

allows the apparatus to be used in procedures in which the mesh patch is to be deployed in a plane that lies at an angle to the longitudinal axis of the cannula.

If the balloon 11 is made of an elastic material, the mesh patch 25 should be attached to the balloon at a single point. If the balloon is made of an inelastic material, the envelope of the balloon does not expand when the balloon in inflated, and the mesh patch may be attached to the balloon at more than one point.

The mesh patch 25 is preferably attached to the balloon 11 by a spot of silicone adhesive 49, as shown in Figures 3A and 3B, or by a spot of a soluble adhesive or other suitable material. The method of detaching the mesh patch from the balloon after deployment will be described below.

Alternatively, the mechanical attachment means can be used to secure the mesh patch 25 to the balloon 11. For example, a small piece of the hook component 51 of a hook and loop connector, such at that sold under the trademark "Velcro," may be attached to the balloon 11, as shown in Figure 4. The hook component is attached to the balloon by means of a suitable adhesive, such as a silicone adhesive. The weave of the mesh patch 25 is sufficiently open that the hooks of the hook component can engage with the mesh patch. This attaches the mesh patch to the hook component, and, hence, to the balloon. The method of detaching the mesh patch from the balloon after deployment will be described below.

The mesh patch 25 may alternatively be attached to the balloon 11 by a hook arrangement such as that shown in Figure 5. In the arrangement shown in Figure 5, the block 53 is attached to the balloon 11, using, for example, a suitable adhesive such as a silicone adhesive. The spring hook 55 slides in the bore 57 in the block, and is formed with the hook portion 59, the distal end 61 of which engages with the blind bore 63 in the block. The spring hook 55 passes through the balloon 11, which forms a fluid-tight seal with the spring hook, and thence up the bore of the cannula (not shown in Figure 5) to a point outside the flap valve (not shown).

To engage the mesh patch 25, the spring hook 55 is withdrawn slightly from the block 53 to disengage for the distal end 61 from the blind bore 63. The distal end is then hooked through the mesh patch 25 as shown, and the spring hook is re-advanced to re-engage the distal end 61 into the blind bore.

To disengage the mesh patch 25 from the hook portion 59 after the mesh patch has been correctly positioned, the endoscope E is advanced distally to brace the block 53 from inside the balloon 11. The proximal part of the spring hook 55 projecting from the flap valve (not shown) is pulled proximally to disengage the distal end 61 of the spring hook progressively from the blind bore 63, the mesh patch 25, and the bore 57. This releases the wire mesh from the mesh delivery apparatus 1. The spring hook is then withdrawn from the interior of the balloon 11 via the cannula 13. The material of the balloon seals the hole formerly occupied by the spring hook.

An additional way of attaching the mesh patch 25 to the mesh delivery apparatus 1 is shown in Figures 6A-6C. A side view of the apparatus is shown in Figure 6A. The strings 71 and 73 are looped through the mesh patch 25 as shown in Figure 6B. The strings are looped as shown so that each string can be disengaged from the mesh patch simply by releasing one of its ends, and pulling on the other end. Figure 6A shows the two strings 71 and 73 looped through the corners of the rectangular mesh patch 25. The number of strings and their position of engagement with the mesh patch can vary according to the size and shape of the

mesh patch.

The cannula 113 is fitted with the O-ring 75. Distal sliding of the O-ring is prevented by the O-ring stops 77. The O-ring stops may form part of the molding of the cannula 113, or may be formed separately and attached to the cannula.

The mesh patch 25 is preferably roughly centered on the center of uninflated balloon 11, and is drawn back along the outside of the cannula 13, as shown in Figure 1B. To minimize the diameter of the mesh delivery apparatus, the mesh patch is preferably spirally wrapped around the outside of the cannula. The strings 71 and 73 are arranged so that they run proximally along the outer surface of the cannula, and then run between the O-ring 75 and the outer surface of the cannula, as shown in Figure 6A. Finally, the strings run further proximally along the outer surface of the port 15 and the handle 23. The strings are pulled distally through the O-ring until the portions of the strings between the mesh patch 25 and the O-ring 75 are slightly in tension. Friction imposed on the strings by the O-ring maintains the tension on the strings. The sleeve 27 may be used to maintain the mesh patch, the strings, and, if the balloon is made of an inelastic material, the balloon, in their wrapped condition. The sleeve 27 will be described in more detail below.

When the balloon 11 is inflated to deploy the mesh patch 25, as will be described in detail below, the axial and lateral expansion of the balloon spreads the mesh patch, which causes the stings 71 and 73 to slide distally through the O-ring 75, as indicated by the arrows 76 shown in Figure 6C. Friction imposed on the strings by the O-ring maintains the strings in tension. The tension on the strings holds the mesh patch firmly in contact with the surface of the balloon 11 as the balloon expands. The mesh delivery apparatus 1 can then be manipulated, if necessary, to optimize the positioning of the mesh patch relative to the site of surgery.

When the mesh patch 25 is optimally positioned, the mesh delivery apparatus 1 is advanced distally to hold the mesh patch between the balloon 11 and the site of surgery. One end of each of the strings 71 and 73 is then pulled proximally to disengage the strings from the mesh patch, as described above. This releases the mesh patch from the mesh delivery apparatus, and allows the mesh delivery apparatus to withdrawn, leaving the mesh patch in place covering the site of surgery, as will be described in more detail below.

Attaching the mesh patch 25 to the mesh delivery apparatus 1 in one of the ways described above, or in some other suitable way, enables the surgeon to use the mesh delivery apparatus to control the position and the angular orientation of the mesh patch 25 relative to the site of surgery. This, in turn, allows a mesh patch to be used with a size and shape optimized for the procedure.

Returning now to Figures 1A-1C, the mesh deliver apparatus 1 may include the sleeve 27 to maintain the mesh patch 25 in its wrapped condition on the outside of the balloon 11 and the cannula 13. The sleeve 27 is generally an elongate bag of a suitable material, such as polyethylene. The sleeve includes the longitudinal slit 29. Opposite edges of the slit 29 are held together by the detachable lacing 31.

The sleeve 27 holds the mesh patch 25 in a compact state while the mesh patch is delivered to the site of surgery in the body, prior to deployment. The sleeve, together with the blunt-tipped obturator 19, provides the packaged mesh delivery apparatus 1 with a firm, rounded nose, and a smooth, tough, outer surface, which enable the mesh delivery apparatus 1 to be used to perform any blunt dissection required in the course of delivering the mesh

mesh patch.

The cannula 113 is fitted with the O-ring 75. Distal sliding of the O-ring is prevented by the O-ring stops 77. The O-ring stops may form part of the molding of the cannula 113, or may be formed separately and attached to the cannula.

The mesh patch 25 is preferably roughly centered on the center of uninflated balloon 11, and is drawn back along the outside of the cannula 13, as shown in Figure 1B. To minimize the diameter of the mesh delivery apparatus, the mesh patch is preferably spirally wrapped around the outside of the cannula. The strings 71 and 73 are arranged so that they run proximally along the outer surface of the cannula, and then run between the O-ring 75 and the outer surface of the cannula, as shown in Figure 6A. Finally, the strings run further proximally along the outer surface of the port 15 and the handle 23. The strings are pulled distally through the O-ring until the portions of the strings between the mesh patch 25 and the O-ring 75 are slightly in tension. Friction imposed on the strings by the O-ring maintains the tension on the strings. The sleeve 27 may be used to maintain the mesh patch, the strings, and, if the balloon is made of an inelastic material, the balloon, in their wrapped condition. The sleeve 27 will be described in more detail below.

When the balloon 11 is inflated to deploy the mesh patch 25, as will be described in detail below, the axial and lateral expansion of the balloon spreads the mesh patch, which causes the stings 71 and 73 to slide distally through the O-ring 75, as indicated by the arrows 76 shown in Figure 6C. Friction imposed on the strings by the O-ring maintains the strings in tension. The tension on the strings holds the mesh patch firmly in contact with the surface of the balloon 11 as the balloon expands. The mesh delivery apparatus 1 can then be manipulated, if necessary, to optimize the positioning of the mesh patch relative to the site of surgery.

When the mesh patch 25 is optimally positioned, the mesh delivery apparatus 1 is advanced distally to hold the mesh patch between the balloon 11 and the site of surgery. One end of each of the strings 71 and 73 is then pulled proximally to disengage the strings from the mesh patch, as described above. This releases the mesh patch from the mesh delivery apparatus, and allows the mesh delivery apparatus to withdrawn, leaving the mesh patch in place covering the site of surgery, as will be described in more detail below.

Attaching the mesh patch 25 to the mesh delivery apparatus 1 in one of the ways described above, or in some other suitable way, enables the surgeon to use the mesh delivery apparatus to control the position and the angular orientation of the mesh patch 25 relative to the site of surgery. This, in turn, allows a mesh patch to be used with a size and shape optimized for the procedure.

Returning now to Figures 1A-1C, the mesh deliver apparatus 1 may include the sleeve 27 to maintain the mesh patch 25 in its wrapped condition on the outside of the balloon 11 and the cannula 13. The sleeve 27 is generally an elongate bag of a suitable material, such as polyethylene. The sleeve includes the longitudinal slit 29. Opposite edges of the slit 29 are held together by the detachable lacing 31.

The sleeve 27 holds the mesh patch 25 in a compact state while the mesh patch is delivered to the site of surgery in the body, prior to deployment. The sleeve, together with the blunt-tipped obturator 19, provides the packaged mesh delivery apparatus 1 with a firm, rounded nose, and a smooth, tough, outer surface, which enable the mesh delivery apparatus 1 to be used to perform any blunt dissection required in the course of delivering the mesh

patch from the insertion point (e.g., an incision at the umbilicus) to the site of surgery where the mesh patch will be used (e.g., the site of the hernia). The sleeve 27 allows the mesh delivery apparatus 1 to deliver the mesh patch 25 to the site of surgery directly through the patient's skin, without the need for a trocar tube. This, in turn, allows the mesh delivery apparatus 1 to deliver larger mesh patches than can be delivered by conventional means, because the diameter of the mesh delivery apparatus in its packaged state is not limited by a requirement that the packaged mesh delivery apparatus be capable of fitting through a trocar tube of a certain diameter.

The detachable lacing 31 includes the release 33, which runs proximally up the outside of the cannula 13, the port 15, and the handle 23. The distal part 35 of the detachable lacing is firmly attached to the sleeve 27. Pulling on the release 33 detaches the detachable lacing 31 from the sleeve 27, which allows the slit 29 to open. Pulling further on the release pulls the sleeve off the mesh patch and the cannula, because the distal part 35 of the lacing remains attached to the sleeve. Pulling yet further on the release 33 enables the surgeon to withdraw the used sleeve from the patient's body.

An alternative structure of the sleeve is shown in Figures 7A and 7B. In Figures 7A and 7B, parts corresponding to those shown in Figures 1A and 1B are indicated by the same reference numbers. In this embodiment, the structure of the cannula 13 and balloon 11, and way in which the mesh patch 25 is wrapped around the balloon and the cannula are the same as that described above with reference to Figures 1A-1C, and will not be described again here. The alternative sleeve 127 is formed with opposed sets perforations 43 and 45 along its length. The perforations do not extend across the distal end of the sleeve 127, so that when the sleeve 127 ruptures along the perforations, the sleeve 127 remains in one piece. Fewer or more sets of perforations may be provided. The sleeve 127 is also formed with the extended portion 47 extending proximally up the outside of the cannula 13, the port 15, and the handle 23.

The sleeve 127 is detached from the mesh delivery apparatus 1 by partially inflating the balloon 11. The expansion of the balloon 11 causes the sleeve 127 to rupture along the perforations 43 and 45, which releases the mesh patch 25 from its packaged state. The balloon can then be expanded further to deploy the mesh patch. After the sleeve has ruptured along the perforations 43 and 45, the surgeon can grip the extended portion 47 close to the handle 23, and, by pulling proximally on the extended portion, can withdraw the used sleeve from the patient's body.

The embodiment of the sleeve 27 shown in Figures 1A-1C can be formed with an extended portion similar to the extended portion 47 shown in Figure 7A. If the sleeve 27 is formed in this manner, the extended portion is used to withdraw the used sleeve from the patient's body, and the distal part 35 of the detachable lacing need not be attached to the sleeve. Alternatively, the sleeve 127 shown in Figures 7A and 7B may be formed without the extended portion 47. In this case, the sleeve must be attached to a draw string (not shown) running up the side of the cannula 13, the port 15, and the handle 23 to enable the surgeon to withdraw the used sleeve from the patient's body.

The balloon 11 may be molded to include the attachment point 37, as shown in Figure 8. Alternatively, a separately-formed attachment point or seat may be attached to part of the balloon using, for example, a suitable adhesive. The attachment point or seat is formed to receive the endoscope E, and includes the portion 39 that has a known optical characteristic.

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The portion 39 with the known optical characteristic enables the endoscope E to provide observation through the distal end of the mesh delivery apparatus 1.

The endoscope E may include the outer sleeve 41 that slides axially on the outer surface of the endoscope E to release the endoscope from the attachment point 37. The endoscope E is inserted through the flap valve (not shown) on the port 15 into the cannula 13 and is removably engaged with the attachment point after the blunt-tipped obturator 19 has been withdrawn from the cannula.

Methods of using the mesh delivery apparatus 1 to deliver a mesh patch directly through the patient's skin in the course of a laparoscopic properitoneal repair of an inguinal hernia will now be described with reference to Figures 9A-9I. In the procedure shown in Figures 9A-9I, the surgeon first makes an incision I at the umbilicus U, and dissects the peritoneum P away from the properitoneal layer PL of the abdominal wall AW to create a working space WS, centered on the site of the hernia H. The preferred method of creating the working space WS by repetitively inflating a suitable balloon to perform blunt dissection is described in United States patent application serial no. 07/911,714, the disclosure of which is incorporated herein by reference. The preferred method results in the working space connected to the incision I by the tunnel TU. The working space WS can also be created using other suitable blunt dissection techniques. The working space can extend as far as the incision I.

During treatment of the site of the hernia prior to using the mesh delivery apparatus 1 to introduce the mesh patch into the working space, the surgeon may insufflate the working space, but should release the insufflation prior to introducing the mesh patch.

Figures 9A and 9B are a vertical cross section and a plan view of the lower abdomen showing the working space prior to inserting the mesh delivery apparatus. In Figure 9B, the boundary of the dissected portion of the peritoneum P is indicated by the broken line 102.

At the point in the procedure at which the mesh patch is to be applied to the site of the hernia H, the surgeon inserts the distal end 104 of the mesh delivery apparatus 1 into the incision I. The mesh delivery is in its packaged state, as shown in Figures 7A, 7B and 1B. Thus, the mesh delivery apparatus 1 includes the blunt-tipped obturator 19 inserted into the cannula 13, such that the distal tip 21 of the obturator projects beyond the distal tip of the cannula, as shown in Figure 1B. The blunt-tipped obturator provides the mesh delivery apparatus 1 with a firm, rounded nose 104 that makes it easier for the surgeon to insert the apparatus into the incision, and to use the apparatus to perform blunt dissection, if required to create or expand the tunnel TU.

The surgeon manipulates the handle 23 of the blunt-tipped obturator 19 inserted into the mesh delivery apparatus 1 to guide the distal end 104 through the tunnel TU towards the working space WS. The mesh delivery apparatus is shown partly advanced through the tunnel in Figure 9C. If the circumference of the tunnel is smaller than the circumference of the mesh delivery apparatus, the rounded distal tip 104 of the apparatus gently dissects more of the peritoneum away from the properitoneal layer of the abdominal wall to enlarge the tunnel to accommodate the mesh delivery apparatus.

When the distal tip 104 of the mesh delivery apparatus 1 is fully advanced into the working space WS, the surgeon substitutes the endoscope E for the blunt-tipped obturator 19 in the cannula 13, as shown in Figure 9D. The endoscope E is advanced to engage in the attachment point 37 (see Figure 8) to enable the surgeon to use the endoscope to observe the position of the distal tip of the mesh delivery apparatus (and, hence, the position of the center

of the mesh patch) relative to the site of the hernia H. Observation is provided through the materials of the balloon, the mesh patch, and the sleeve 127. The observation feature allows the surgeon to obtain accurate positioning not available with conventional techniques.

A supply (not shown) of a suitable inflation fluid, such as air, nitrogen, carbon dioxide, or saline, etc. is connected to the valve 17 on the port 15, and the inflation fluid supply is turned on to partially inflate the balloon 11. The resulting expansion of the balloon causes the sleeve 127 to rupture along the perforations 43 and 45. The surgeon grips the extended portion 47 of the sleeve lying close to the port 15 outside the tunnel TU and pulls the extended portion proximally to withdraw the sleeve 127 from out of the tunnel TU, as shown in Figure 9E.

Partially inflating the balloon also partly releases the mesh patch 25 from its wrapped condition around the cannula 13, as shown in Figure 9F. The surgeon then manipulates the port 15 of the mesh delivery apparatus 1, while observing using the endoscope E, to center the endoscope on the site of the hernia H, or to position the endoscope otherwise relative to the site of the hernia. Since the endoscope is approximately centered in the mesh patch 25, centering the endoscope of the site of the hernia automatically centers the mesh patch 25 on the site of the hernia.

The supply of inflation fluid is turned on once again to expand the balloon 11 to its fully expanded condition, as shown in Figure 9G. Expanding the balloon to its fully-expanded condition fully releases the mesh patch from the cannula 13, and flattens the mesh patch against the properitoneal layer PL of the abdominal wall surrounding the site of the hernia H.

Inflation fluid is then partially released or evacuated from the balloon 11 to deflate the balloon to about half its maximum volume. Despite the partial deflation of the balloon, the mesh patch 25 remains in its fully deployed condition, in contact with the abdominal wall, as shown in Figure 9H.

If the mesh patch is attached to the mesh delivery apparatus 1, the surgeon releases the mesh patch from the mesh delivery apparatus with the balloon 11 in its partly-inflated condition. The procedure for releasing the mesh patch depends on the way in which the mesh patch is attached to the apparatus. The procedures for releasing the mesh patch when the mesh patch is attached to the balloon 11 by the spring hook 55 (Figure 5) or by the strings 71 and 73 (Figures 6A-6C) have been described above. The procedure for releasing the mesh patch when the mesh patch is attached to the balloon 11 by an adhesive (Figure 3A) or by the hook component of a hook-and-loop connector (Figure 4) will now be described.

A second small incision I2 is made through the abdominal wall near the site of the hernia, as shown in Figure 9I. An elongate probe PR is driven through the abdominal wall at the incision I2. While observing the distal end of the probe through the endoscope E inside the partially-inflated balloon 11, the surgeon manipulates the proximal end of the probe to locate the distal end 106 of the probe between the partially-expanded balloon 11 and the mesh patch 25. Then, the surgeon manipulates the proximal end to locate the distal end 106 adjacent the attachment point A between the mesh patch and the balloon.

When the probe PR is properly located, the surgeon applies pressure to the probe PR to move the distal tip 106 of the probe and the mesh patch 25 towards the properitoneal layer PL of the abdominal wall. At the same time, the surgeon gently draws the mesh delivery apparatus 1 away from the properitoneal layer PL. The probe prevents the mesh patch from following the balloon 11 of the mesh delivery apparatus, which breaks the attachment

between mesh patch and the balloon.

Once the balloon 11 is detached from the mesh patch 25, the surgeon can deflate the balloon 11 fully, withdraw the mesh delivery apparatus 1 from the incision I, and withdraw the probe PR from the incision I2. During this part of the procedure, the mesh patch stays in place over the site of the hernia H.

The working space WS then may be re-insufflated, and the mesh patch, which has remained in position over the site of the hernia, can then be stapled or otherwise secured to the abdominal wall in the conventional manner. Alternatively, the mesh patch may be left unattached to the abdominal wall, and reattachment of the peritoneum to the properitoneal layer of the abdominal wall following the surgery can be relied upon to retain the mesh patch in position over the site of the hernia.

The procedure just described is performed using the mesh delivery apparatus with the embodiment of the sleeve shown in Figures 7A and 7B. The procedure could equally well be performed using the mesh delivery apparatus with the embodiment of the sleeve shown in Figures 1A-1C. Moreover, the procedure just described could be performed using a mesh delivery apparatus in which the mesh patch is unattached to the mesh delivery apparatus, or using a mesh delivery apparatus in which the mesh patch is attached to the mesh delivery apparatus in any of the ways described above, or in other ways.

Procedures based on the procedure described above could use any of the embodiments of the mesh delivery apparatus described above to deploy a mesh patch in the course of a conventional laparoscopic (non-properitoneal) hernia repair. Procedures based on the procedure described above could use any of the embodiments of the mesh delivery apparatus described above to deploy a mesh patch in the course of other laparoscopic procedures. Procedures based on the procedure described above could use any of the embodiments of the mesh delivery apparatus described above to deliver a mesh patch in the course of an conventional (non-laparoscopic) procedure in which a mesh patch is applied to a site of surgery.

An alternative hernia repair procedure is shown in Figures 10A-10F. In this procedure, the working space WS is created and maintained using a structural balloon, such as one of the structural balloons described in United States patent no. 5,309,896, and United States patent application serial no. 08/134,573. The structural balloon is used to create the working space using the technique described in United States patent application serial no. 08/134,573, the disclosure of which is incorporated herein by reference.

Figure 10A shows the working space being maintained by the large structural balloon SB of the type described in United States patent application serial no. 08/134,573. The main chamber of the structural balloon has been expanded to dissect the peritoneum P from the properitoneal layer PL and to create the working space; the secondary chamber has been expanded to maintain the working space; the inflation pressure in the main chamber has been released; and, finally, the large front window W in the structural balloon has been opened to provide access to the site of the hernia H.

The structural balloon SB also includes a number of top and side windows, such as the top window TW, through which instruments can be passed into the interior of the structural balloon. The instruments can then pass out of the large front window W to operate at the site of the hernia. General observation of the procedure is provided by the endoscope E2 passed through the inflation tube T of the structural balloon.

At the point in the procedure at which the mesh patch is to be placed over the site of the hernia H, the surgeon makes a short incision I through the abdominal wall AW adjacent the top window TW. The surgeon continues the incision to pierce an aperture in the top window TW, as shown in Figure 10B. This step may be unnecessary if a suitable incision extending through the abdominal wall and the top window has been made earlier in the procedure.

The surgeon inserts the distal end 104 of the mesh delivery apparatus 1, in its packaged state as shown in Figures 1A-1C, into the incision I, and thrusts the distal end through the incision into the interior of the structural balloon SB, as shown in Figure 10C. In its packaged state, the mesh delivery apparatus 1 includes the blunt-tipped obturator 19 inserted into the cannula 13, such that the distal tip 21 of the obturator projects beyond the distal tip of the cannula, as shown in Figure 1B. The blunt-tipped obturator provides the mesh delivery apparatus 1 with a firm, rounded nose 104 that makes it easier to insert the apparatus into the structural balloon SB through the incision I and can provide additional blunt dissection if desired.

The surgeon then pulls the release 33 proximally to detach the lacing 31 from the sleeve 27. This releases the sleeve 27 from around the mesh patch 25. The surgeon pulls the release further to remove the sleeve from the interior of the structural balloon SB by drawing the sleeve through the incision in the top window TW, and through the incision I, outside the cannula 13, as shown in Figure 10D. Releasing the sleeve from around the mesh patch 25 partly releases the mesh patch from its wrapped condition around the cannula 13.

The surgeon substitutes the endoscope E1 for the blunt-tipped obturator 19 in the cannula 13. The surgeon advances the endoscope E1 to engage in the attachment point 37 (Figure 8). This enables the surgeon to use the endoscope to observe the position of the distal tip of the apparatus relative to the site of the hernia H. The surgeon then manipulates the proximal part of the mesh delivery apparatus 1 to advance the distal part of the apparatus distally through the front window W of the structural balloon SB towards the site of the hernia.

A supply (not shown) of a suitable inflation fluid, such as air, nitrogen, carbon dioxide, or saline, is attached to the valve 17 on the port 15, and the supply is turned on to partially inflate the balloon 11. Partial inflation of the balloon further releases the mesh patch from its wrapped condition around the cannula 13. The surgeon then manipulates the proximal part of the mesh delivery apparatus 1, while observing using the endoscope E1, to center the endoscope on the site of the hernia H. Since the endoscope is approximately centered in the mesh patch, this automatically centers the mesh patch 25 on the site of the hernia.

Once the surgeon has correctly positioned the endoscope E, and hence the mesh patch 25, relative to the site of the hernia H, the supply of inflation fluid is turned on once again to inflate the balloon 11 to its fully expanded condition. Inflation of the balloon to its fully-expanded condition fully releases the mesh patch from the cannula and flattens the mesh patch against the properitoneal layer of the abdominal wall surrounding the site of the hernia, as shown in Figure 10E.

Inflation fluid is then partially released from the balloon 11 to deflate the balloon to about half its maximum volume. Despite the partial deflation of the balloon, the mesh patch 25 remains in its fully deployed condition, in contact with the properitoneal layer PL of the abdominal wall. With the balloon in its partly-inflated condition, the surgeon releases the mesh patch from the balloon using, if necessary, one of the releasing methods described above. Finally, the surgeon withdraws the mesh delivery apparatus 1 from the incision I, as shown

in Figure 10F.

The mesh patch 25, which remains in position over the site of the hernia H after the mesh delivery apparatus 1 has been withdrawn, is then attached to the abdominal wall in a conventional manner, using instruments passed through the structural balloon SB. This part of the process is observed using the endoscope E2. Alternatively, the mesh patch may be left unattached to the abdominal wall, and reattachment of the peritoneum to the properitoneal layer of the abdominal wall following the surgery is relied upon to retain the mesh patch in position over the site of the hernia.

Following attachment of the mesh patch 25 to the properitoneal layer of the abdominal wall, the inflation of the structural balloon SB is released, and the structural balloon is evacuated. The structural balloon is then withdrawn from the properitoneal space by means of the inflation tube T, and the incisions are closed.

The procedure just described is performed using the mesh delivery apparatus with the embodiment of the sleeve shown in Figures 1A-1C. The procedure could equally well be performed using the mesh delivery apparatus with the embodiment of the sleeve shown in Figures 7A and 7B. Moreover, the procedure just described could be performed using a mesh delivery apparatus in which the mesh patch is unattached to the mesh delivery apparatus, or using a mesh delivery apparatus in which the mesh patch is attached to the mesh delivery apparatus in any of the ways described above, or in other ways. Finally, a procedure similar to that described above could be used to deliver a mesh patch during other surgical procedures.

Although illustrative embodiments of the invention have been described herein in detail, it is to be understood that the invention is not limited to the precise embodiments described, and that various modifications may be practiced within the scope of the invention defined by the appended claims.

Claims

We claim:

1. Apparatus for delivering a mesh patch during a surgical procedure, the apparatus comprising:

an elongate cannula having a distal end; and

a balloon mounted on the distal end of the cannula, the mesh patch being wrapped around part of the cannula and the balloon, the balloon being in a collapsed state.

2. The apparatus of claim 1, additionally comprising attaching means for detachably attaching the mesh patch to the apparatus.

3. The apparatus of claim 2, wherein the attaching means comprises an adhesive disposed between the balloon and the mesh patch.

4. The apparatus of claim 2, wherein the attaching means comprises a hook component of a hook and loop connector affixed to the balloon, the hook component including hooks, the hooks engaging with the mesh patch.

5. The apparatus of claim 2, wherein the attaching means comprises:

a block affixed to the balloon, the block including a bore,

an elongate spring hook including a hook portion, the hook portion releasably engaging the mesh patch, the elongate spring hook sliding axially in the bore to release the mesh patch from the hook portion.

6. The apparatus of claim 2, wherein the attaching means comprises a thread looped through the mesh patch, opposite end portions of the thread running proximally outside the cannula.

7. The apparatus of claim 6, wherein:

the attaching means additionally comprises an O-ring mounted on the cannula; and

the opposite end portions pass between the O-ring and the cannula.

8. The apparatus of claim 1, additionally comprising a detachable sleeve enclosing the balloon and the mesh patch.

9. The apparatus of claim 8, wherein the detachable sleeve includes a lengthways split, the lengthways split being closed by detachable lacing.

10. The apparatus of claim 9, wherein the detachable lacing includes a proximal portion and a distal portion, proximal motion of the proximal portion detaching the detachable lacing from the sleeve, the distal portion being affixed to the sleeve.

11. The apparatus of claim 8, wherein the detachable sleeve includes longitudinal perforations, expansion of the balloon causing the detachable sleeve to split at the perforations.

12. The apparatus of claim 8, additionally comprising withdrawing means for withdrawing the detachable sleeve proximally after detachment from the apparatus.

13. The apparatus of claim 12, wherein the detachable sleeve includes a proximal extension, the proximal extension providing the withdrawing means.

14. The apparatus of claim 8, additionally comprising attaching means for detachably attaching the mesh patch to the apparatus.

15. A method of delivering a mesh patch to a site of surgery inside a patient, the method comprising the steps of:

providing a balloon having the mesh patch wrapped therearound, the balloon being in a collapsed state;

passing the balloon wrapped in the mesh patch through the patient's skin to locate the balloon wrapped in the mesh patch adjacent the site of surgery; and

inflating the balloon to an expanded state, expansion of the balloon to the expanded state opening and flattening the mesh patch to apply the mesh patch to the site of surgery.

16. The method of claim 15, wherein, in the step of providing a balloon having the mesh patch wrapped therearound, there is additionally provided a sleeve enclosing the balloon and the mesh patch.

17. The method of claim 16, wherein the method additionally comprises the step of releasing sleeve from the mesh patch and the balloon after the step of passing the balloon wrapped in the mesh patch through the patient's skin.

18. The method of claim 15, wherein:

in the step of providing a balloon having the mesh patch wrapped therearound, there is provided a balloon mounted on a distal end of an elongate cannula, part of the mesh patch being wrapped around part of the cannula; and

the step of passing the balloon through the patient's skin to locate the balloon adjacent the site of surgery includes the step of manipulating a proximal portion of the elongate cannula.

19. The method of claim 18, wherein:

in the step of providing a balloon having the mesh patch wrapped therearound, there is additionally provided:

a blunt obturator inserted into the elongate cannula and projecting into the balloon, and

a sleeve enclosing the mesh patch, the balloon, and the cannula; and

the step of passing the balloon through the patient's skin includes the step of using the firm, rounded nose provided by the blunt obturator and the sleeve to perform dissection.

20. The method of claim 19, wherein, in the step of passing the balloon through the patient's skin, the sleeve contacts the patient's skin.

21. The method of claim 15, wherein, after the step of inflating the balloon to the expanded state, the method additionally comprises the steps of:

advancing the balloon to bring the deployed mesh patch into contact with the site of surgery; and

withdrawing the balloon, leaving the deployed mesh patch attached to the site of surgery.

22. The method of claim 15, wherein, in the step of providing a balloon having the mesh patch wrapped therearound, the mesh patch is detachably attached to the balloon; and

after the step of inflating the balloon to an expanded state, the method additionally comprises the step of releasing the mesh patch from the balloon.

23. The method of claim 22, wherein, after the step of releasing the mesh patch from the balloon includes the steps of:

advancing the balloon to bring the deployed mesh patch into contact with the site of surgery;

holding the deployed mesh patch in contact with the site of surgery; and

withdrawing the balloon to detach the balloon from the mesh patch, the deployed mesh patch remaining attached to the site of surgery.

24. A method of performing a hernia repair, the method comprising the steps of:

(1) providing a mesh delivery apparatus comprising:

(a) an elongate cannula having a distal end,

(b) a balloon mounted on the distal end of the cannula, the mesh patch being wrapped around the balloon and part of the cannula, and

(c) a detachable sleeve enclosing the balloon and the mesh patch;

(2) creating a working space adjacent the hernia;

(3) inserting a distal part of the mesh delivery apparatus into the working space to locate the balloon adjacent the hernia; and

(4) inflating the balloon to an expanded state, expansion of the balloon to the expanded state opening and flattening the mesh patch ready for applying the mesh patch to cover the hernia.

25. The method of claim 24, wherein, in the step of creating a working space, the working space is created between a peritoneum and a properitoneal layer.

26. The method of claim 24, wherein the step of inserting the distal part of the mesh delivery apparatus includes the steps of:

making an incision into the working space, and

inserting the distal part of the mesh delivery apparatus into the working space through the incision, the mesh delivery apparatus contacting the incision.

27. The method of claim 24, wherein:

in the step of creating a working space, the working space is created by inflating a structural balloon; and

in the step of inserting the distal part of the mesh delivery apparatus into the working space, the distal part of the mesh delivery apparatus is inserted into the working space through a window in the structural balloon.

28. The method of claim 24, wherein, in the step of inserting the distal part of the mesh delivery apparatus, the distal part of the mesh delivery apparatus is inserted into the working space through an elongate tunnel, the mesh delivery apparatus contacting the tunnel.

29. The method of claim 28, wherein:

in the step of providing a mesh delivery apparatus, there is provided a mesh delivery apparatus additionally comprising a blunt obturator inserted into the cannula to project into the balloon, the blunt obturator providing the mesh delivery apparatus with a rounded, firm nose; and

the step of inserting the distal part of the mesh delivery apparatus includes the step of using the mesh delivery apparatus perform blunt dissection to enlarge the tunnel.

30. The method of claim 24, wherein the step of inserting the distal part of the mesh delivery apparatus comprises the steps of:

providing an endoscope, the endoscope having a distal portion;

inserting the distal portion of the endoscope through the cannula into the balloon; and

locating the balloon adjacent the hernia by observation using the endoscope.

31. The method of claim 24, wherein the step of inflating the balloon includes the steps of:

partially inflating the balloon to rupture the detachable sleeve;

removing the ruptured detachable sleeve from the working space; and

fully inflating the balloon to bring the mesh patch into contact with the hernia.

32. The method of claim 24, wherein:

in the step of providing a mesh delivery apparatus, there is provided a mesh delivery apparatus wherein the mesh patch is releasably attached to the balloon; and

after the step of inflating the balloon, the method additionally comprises the step of holding the mesh patch in contact with the hernia; and

withdrawing the mesh delivery apparatus to release the balloon from the mesh patch.

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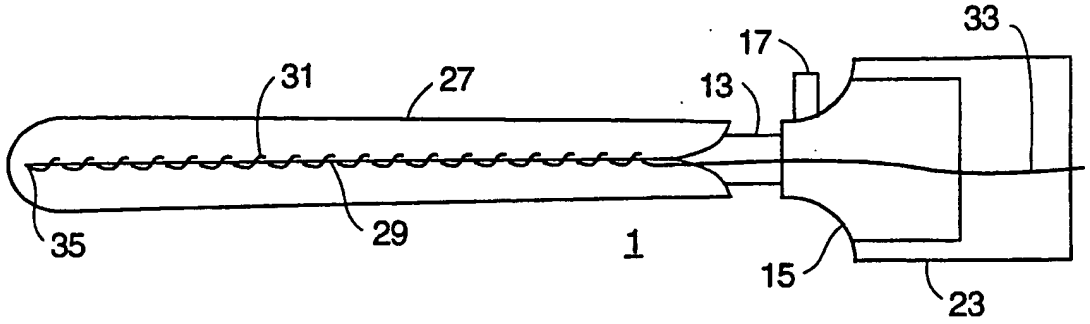

FIG. 1A

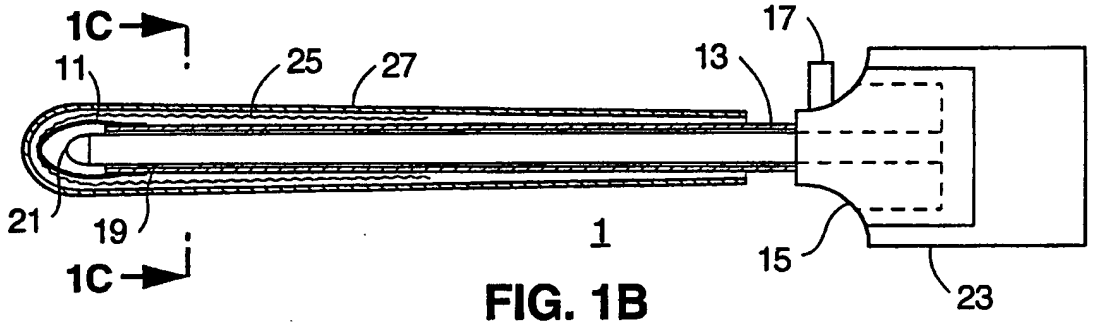

FIG. 1B

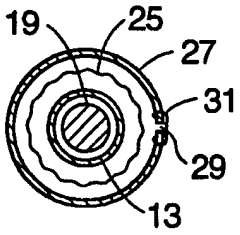

FIG. 1C

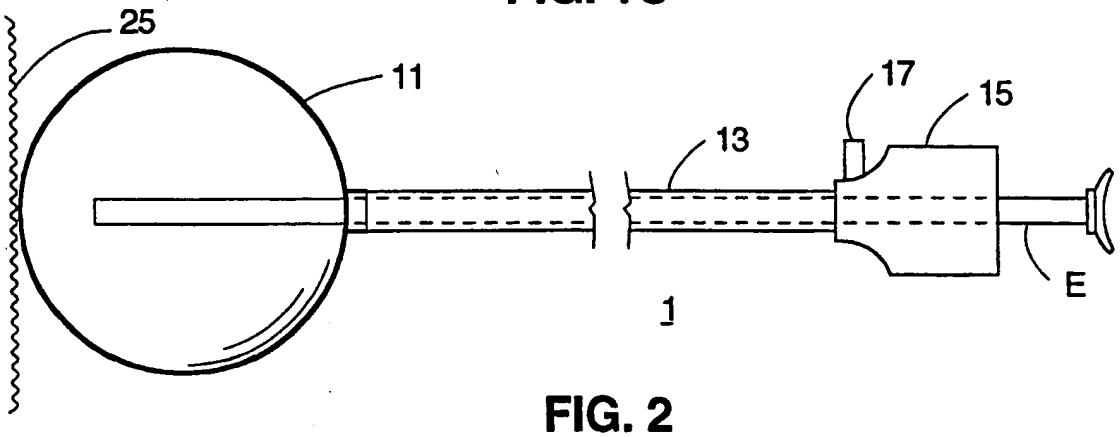

FIG. 2

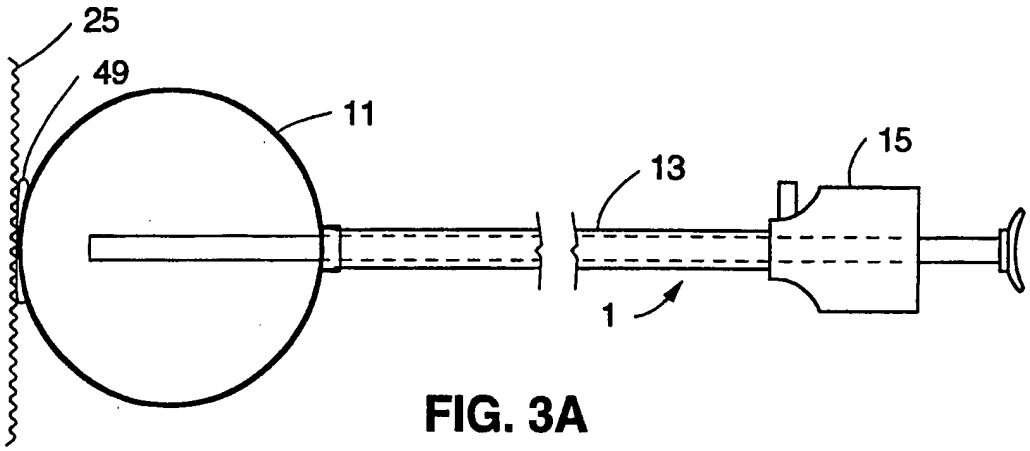

FIG. 3A

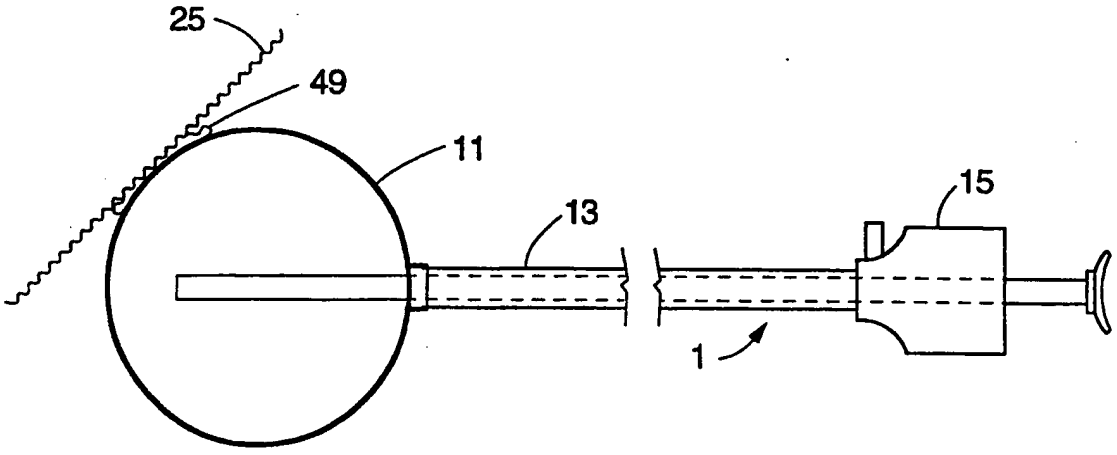

FIG. 3B

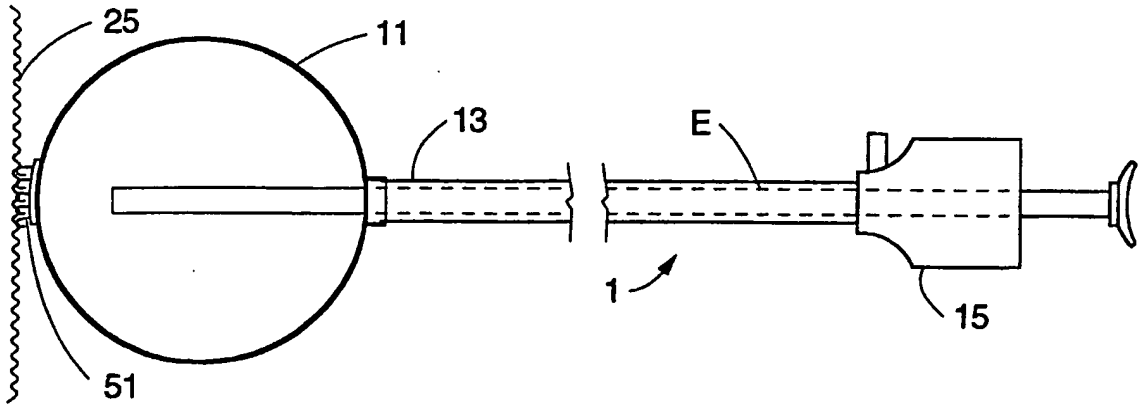

FIG. 4

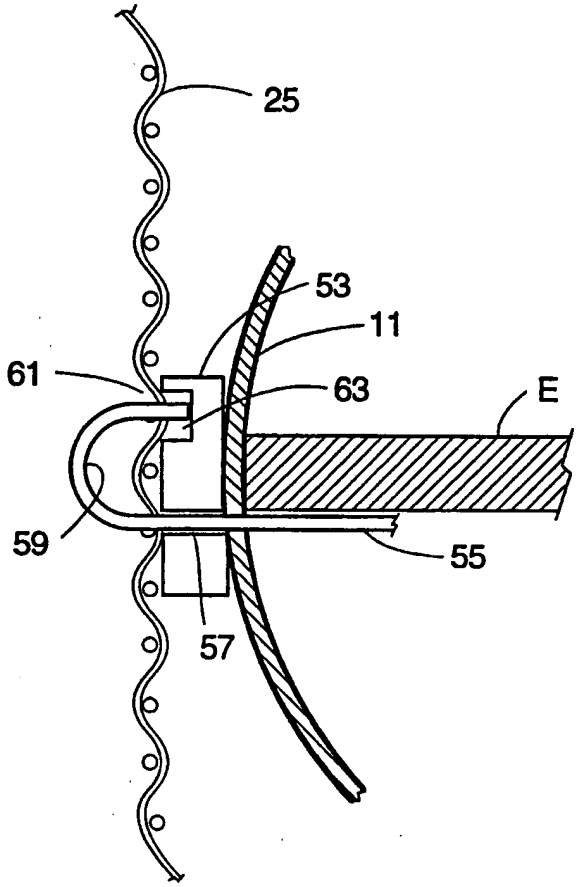

FIG. 5

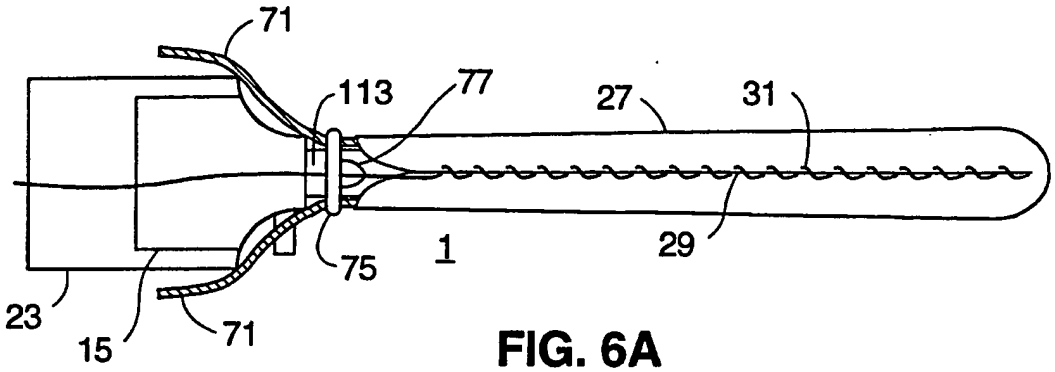

FIG. 6A

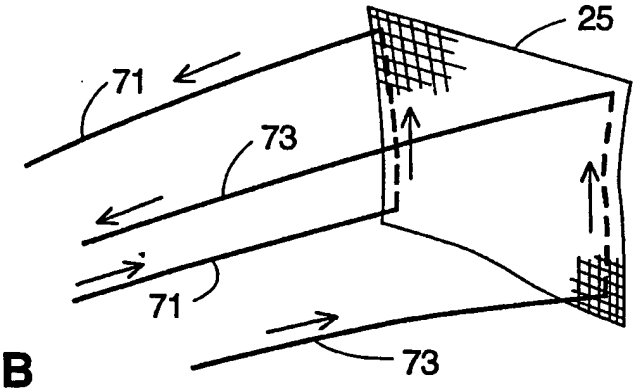

FIG. 6B

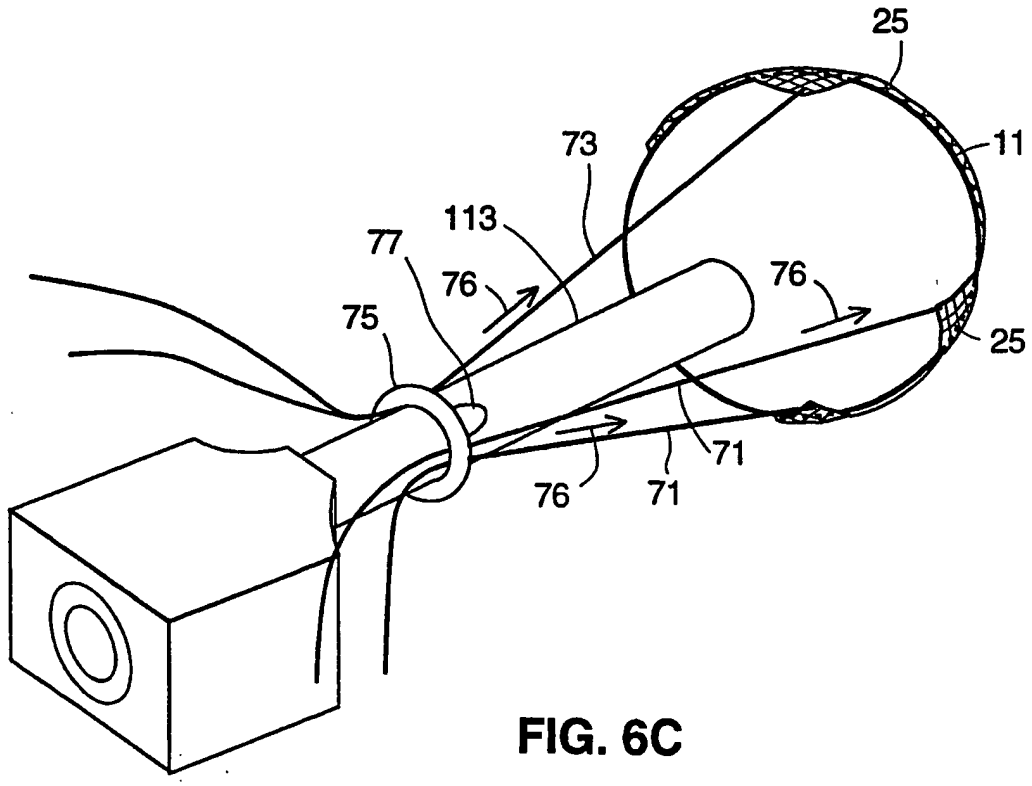

FIG. 6C

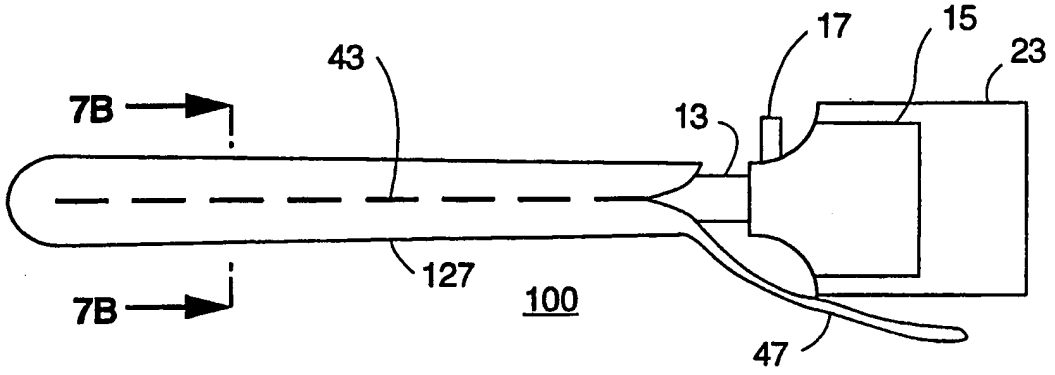

FIG. 7A

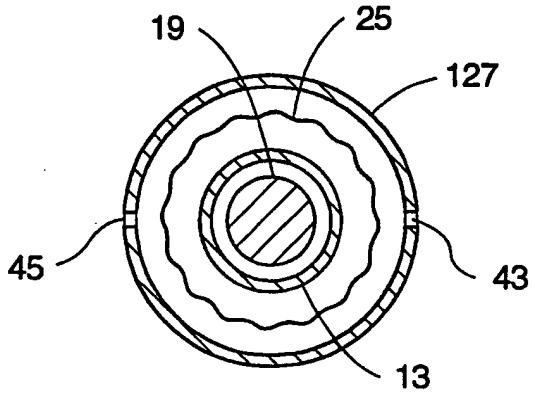

FIG. 7B

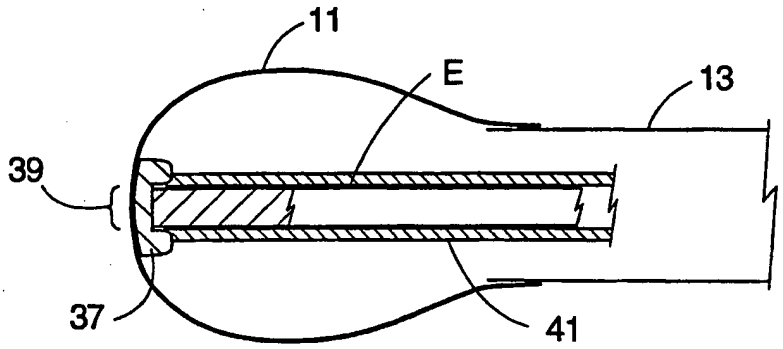

FIG. 8

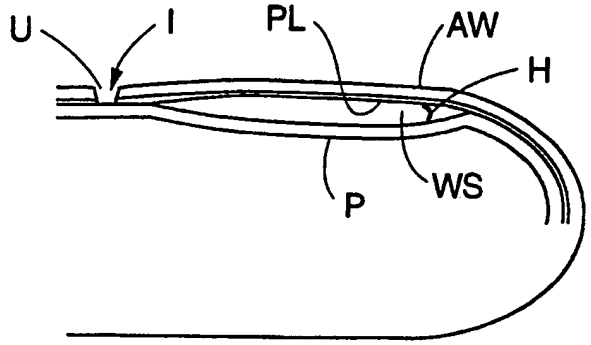

FIG. 9A

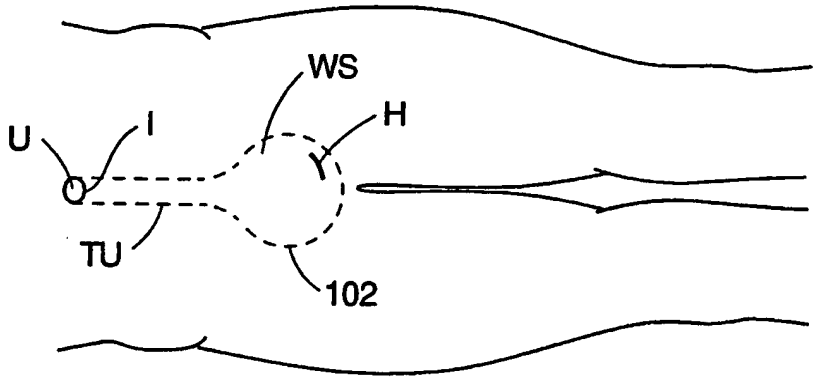

FIG. 9B

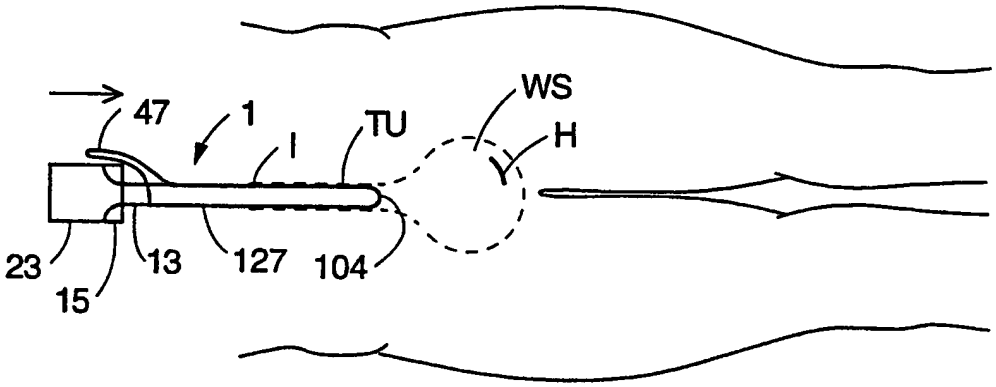

FIG. 9C

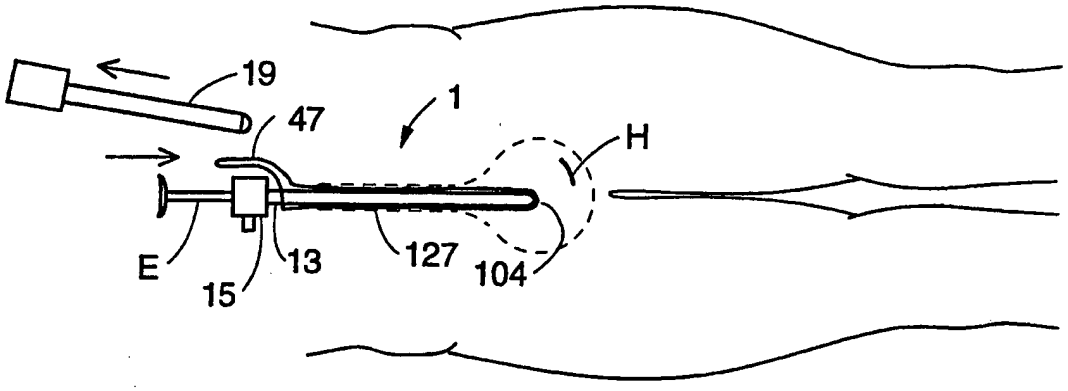

FIG. 9D

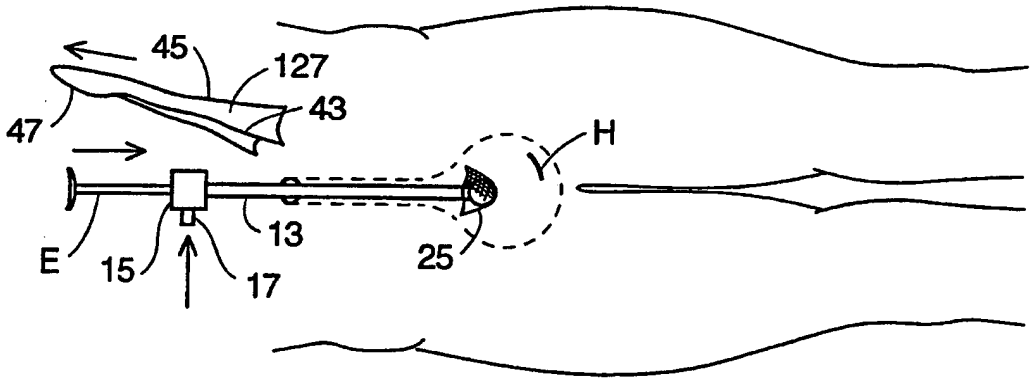

FIG. 9E

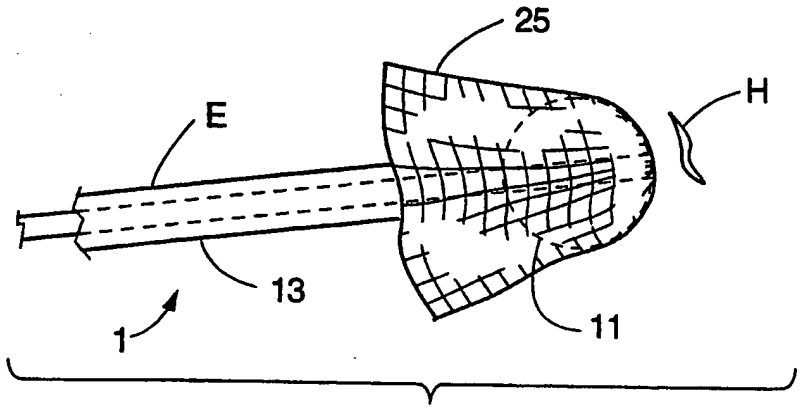

FIG. 9F

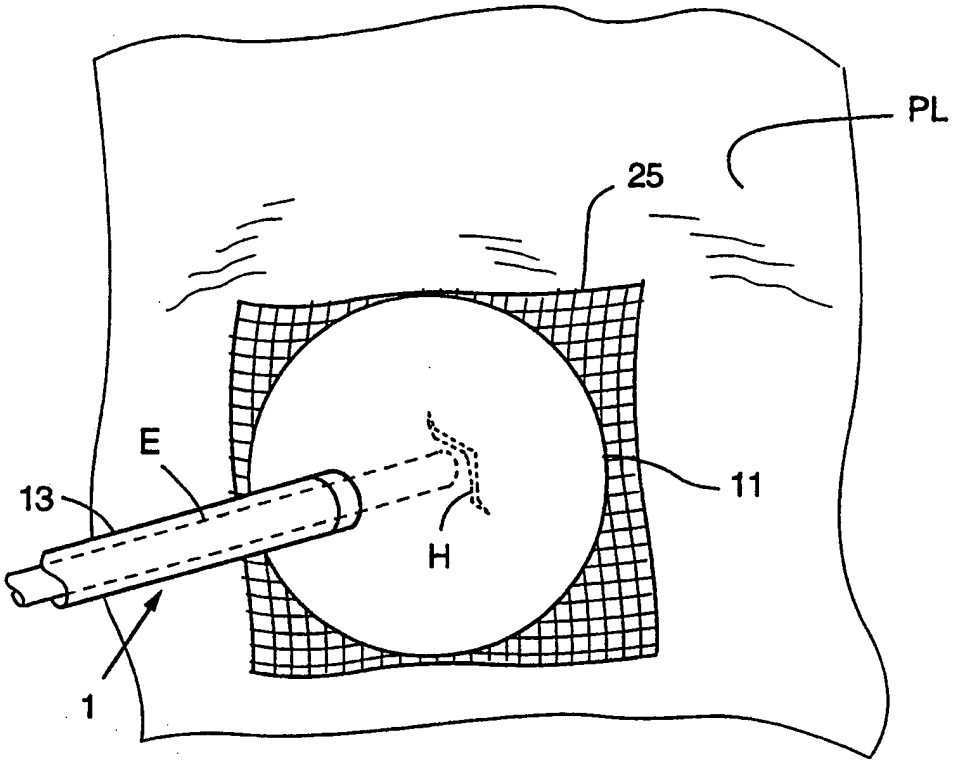

FIG. 9G

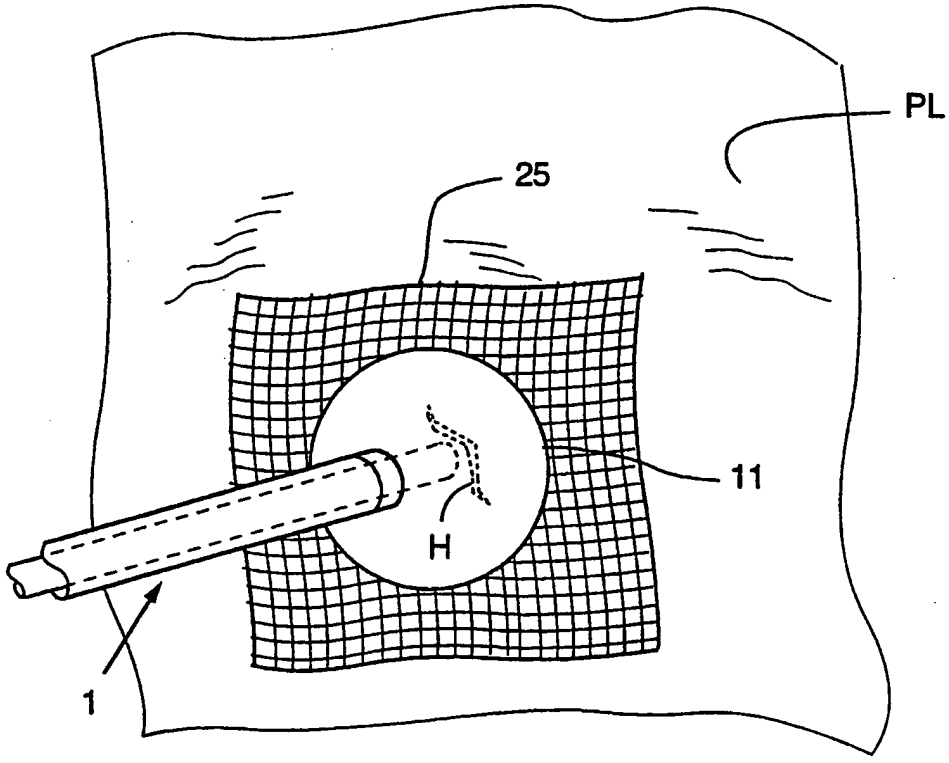

FIG. 9H

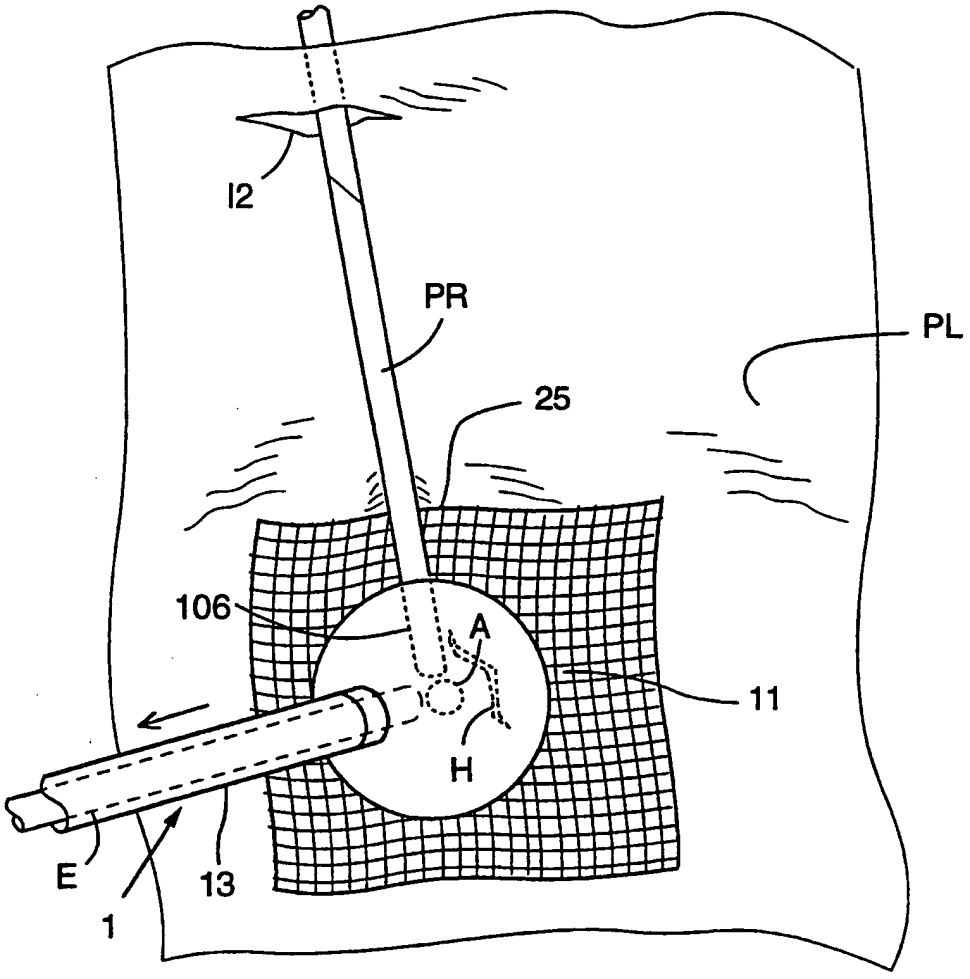

FIG. 9 I

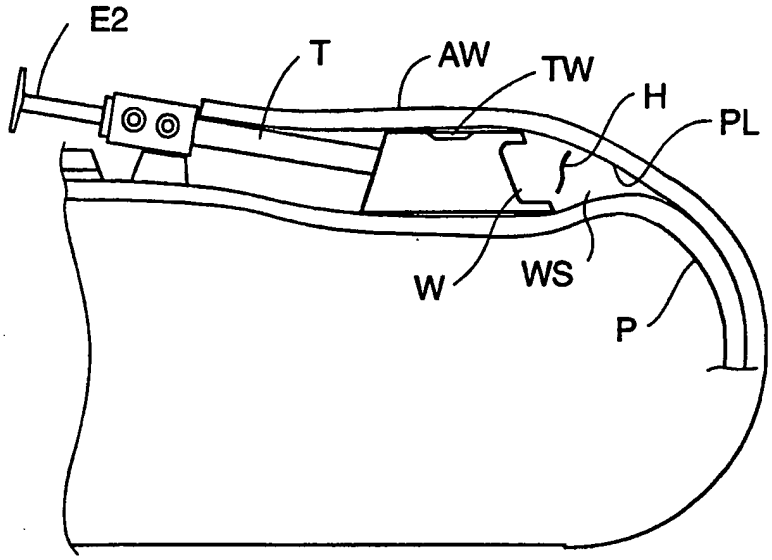

FIG. 10A

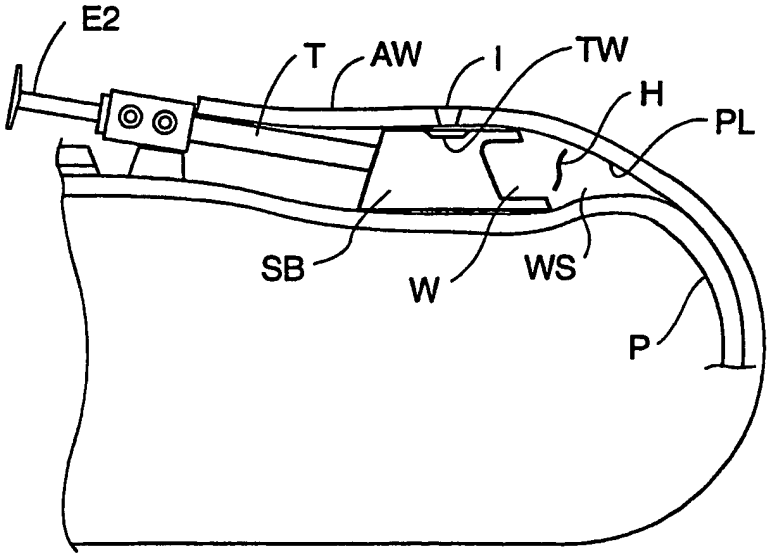

FIG. 10B

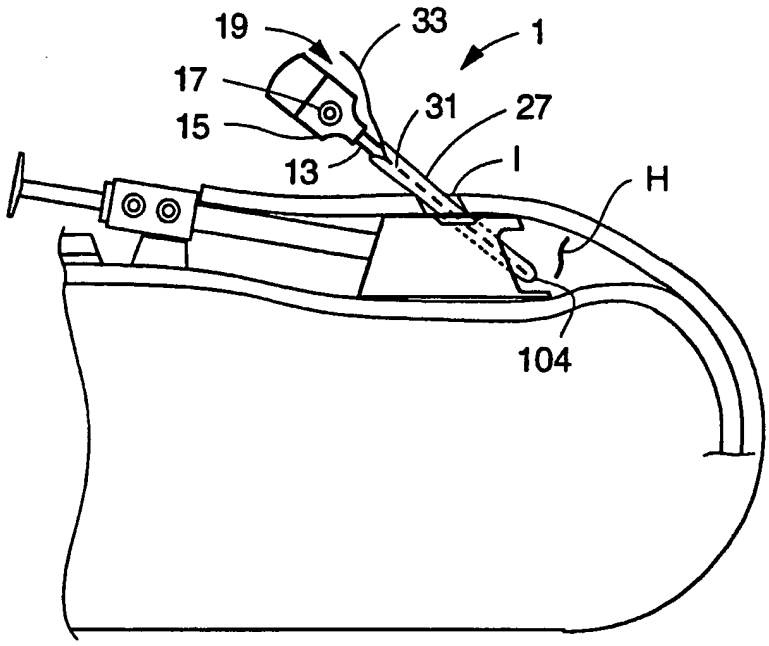

FIG. 10C

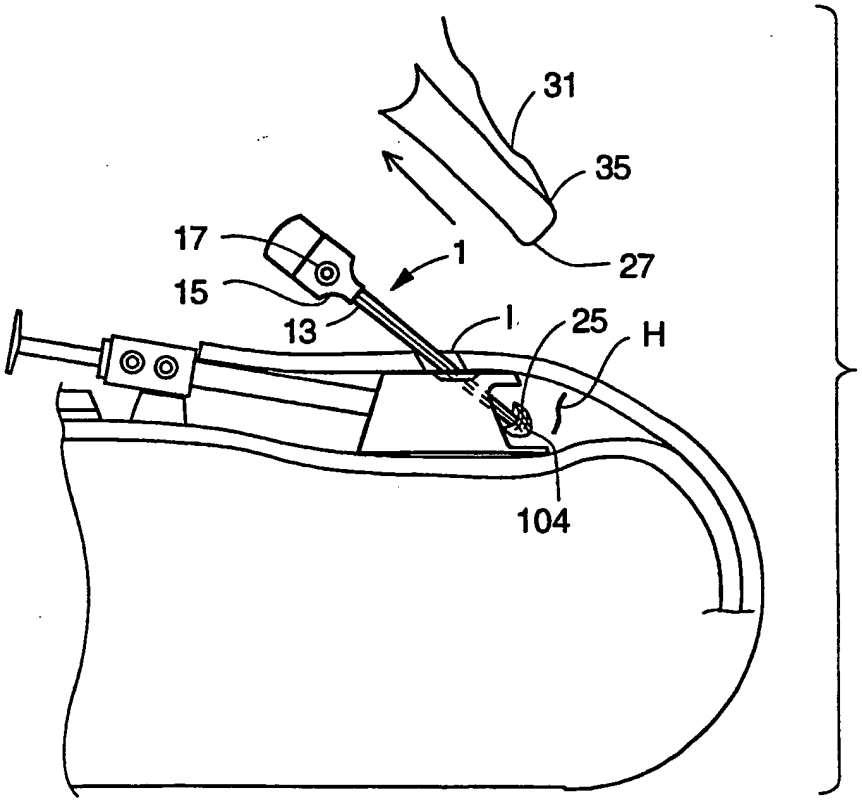

FIG. 10D

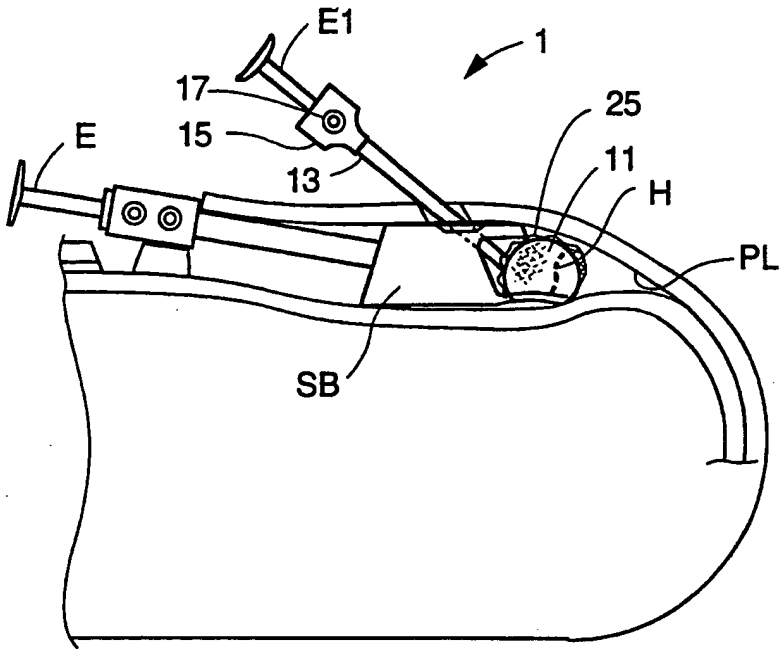

FIG. 10E

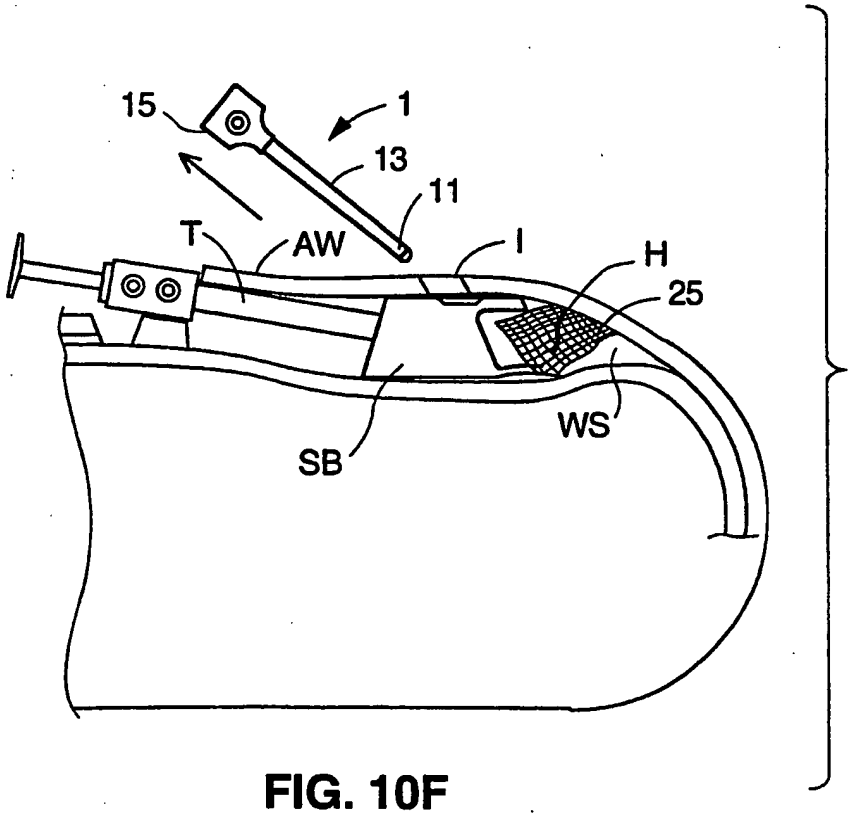

FIG. 10F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/05430

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 17/02
US CL :128/20; 606/151, 192
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/20; 606/151, 192, 213

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	EP, A, 0 573 273 (KLETURAKIS ET AL.) 08 December 1993, see entire document.	1-4, 8-26, 28, 29, 31, 32 --- 6, 7, 27, 30
Y	US, A, 5,116,357 (EBERBACH) 26 May 1992, see entire document.	6, 7
Y	US, A, 3,774,596 (COOK) 27 November 1973, see entire document.	27
Y	US, A, 4,779,611 (GROOTERS ET AL.) 25 October 1988, see entire document.	30

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 28 JUNE 1995	Date of mailing of the international search report 10 JUL 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL THALER Telephone No. (703) 308-2981

Form PCT/ISA/210 (second sheet)(July 1992)*